

AMENDMENT AND RESPONSE TO OFFICE ACTION

Amendment

In The Claims

1. (currently amended) A drug formulation comprising
a drug selected from the group consisting danazol, bromocriptine, and luteinizing
hormone-releasing hormone (LHRH) analogues in an amount effective to provide regional, not
systemic, relief from benign diseases or disorders of the breast
in a pharmaceutically acceptable carrier selected from the group consisting of a gel,
ointment, lotion, emulsion, cream, foam, mousse, liquid, spray, and aerosol capable of delivering
the drug to the breast tissue, comprising a penetration enhancer to promote delivery of the drug
across the stratum corneum, ~~wherein the drug is not a non-steroidal anti-inflammatory or~~
~~analgesic, in a dosage which results in low serum drug levels as compared to the systemic~~
~~administration of the drug.~~

2. (original) The drug formulation of claim 1 wherein the drug is soluble in aqueous
solutions.

3. (original) The drug formulation of claim 1 wherein the drug is in the form of micro- or
nano-particulates.

4. (currently amended) The drug formulation of claim 1 wherein the carrier is selected
from the group consisting of a gel, ~~ointment, lotion, emulsion, cream, foam, mousse, liquid,~~
~~spray, and aerosol.~~

5. (currently amended) The drug formulation of claim 4-3, wherein the carrier is a
hydroalcoholic gel.

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6. (cancelled)

7. (currently amended) The drug formulation of claim 6 1 wherein the drug is selected from the group consisting of danazol, and bromocriptine, ~~tamoxifen~~, luteinizing hormone-releasing hormone (LHRH) analogues, and antiestrogens.

8. (currently amended) The drug formulation of claim 6 3 wherein the drug is a danazol.

9. (cancelled)

10. (withdrawn, currently amended) A method for treating a disease or disorder of the breast comprising

topically administering to the breast of a patient,

a drug formulation suitable for local or regional delivery comprising an effective amount of drug selected from the group consisting of danazol, bromocriptine, and luteinizing hormone-releasing hormone (LHRH) analogues to provide regional, not systemic, relief from benign diseases and disorders of the breast,

in a pharmaceutically acceptable carrier selected from the group consisting of a gel, ointment, lotion, emulsion, cream, foam, mousse, liquid, spray, and aerosol capable of delivering the drug to the breast tissue, comprising a penetration enhancer to promote delivery of the drug across the stratum corneum, ~~wherein the drug is not a non-steroidal anti-inflammatory or analgesic~~, in a dosage which results in low serum drug levels as compared to the systemic administration of the drug.

11. (withdrawn) The method of claim 10 wherein the drug is in the form of micro- or nano-particulates.

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12. (withdrawn, currently amended) The method of claim 10 wherein the carrier is selected from the group consisting of a gel, ointment, lotion, emulsion, cream, foam, mousse, liquid, spray, and aerosol.

13. (cancelled)

14. (withdrawn, previously presented) The method of claim 13 wherein the drug is selected from the group consisting of danazol, and bromocriptine, tamoxifen, luteinizing hormone-releasing hormone (LHRH) analogues, and antiestrogens.

15. (withdrawn, currently amended) The method of claim 13 11 wherein the drug is danazol.

16. (cancelled)

17. (withdrawn, currently amended) The method of claim 10 wherein the benign disease of the breast is selected from the group consisting of mastalgia, mastodynia, Mondor's disease, fibrocystic breast disease, costochondritis, mastitis, Paget's disease of the areola, fibroadenoma, breast abscess, and breast infections.

18. (cancelled)

19. (withdrawn, currently amended) The method of claim 18 10 wherein the region is the breast, areola, and underlying musculature of the chest.